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PRESCRIPTION DRUGS

OxyContin Abuse and Diversion and Efforts to Address the Problem

G A O

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their marketing and promotion were truthful, balanced, and accurately communicated. In addition, Purdue provided two promotional videos to physicians that, according to FDA appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review.

Purdue Focused on Promoting OxyContin for Treatment of Noncancer Pain

From the outset of the OxyContin marketing campaign, Purdue promoted the drug to physicians for noncancer pain conditions that can be caused by arthritis, injuries, and chronic diseases, in addition to cancer pain. Purdue directed its sales representatives to focus on the physicians in their sales territories who were high opioid prescribers. This group included cancer and pain specialists, primary care physicians, and physicians who were high prescribers of Purdue's older product, MS Contin. One of Purdue's goals was to identify primary care physicians who would expand the company's OxyContin prescribing base. Sales representatives were also directed to call on oncology nurses, consultant pharmacists, hospices, hospitals, and nursing homes.

From OxyContin's launch until its July 2001 label change, Purdue used two key promotional messages for primary care physicians and other high prescribers. The first was that physicians should prescribe OxyContin for their pain patients both as the drug "to start with and to stay with." The second contrasted dosing with other opioid pain relievers with OxyContin dosing as "the hard way versus the easy way" to dose because OxyContin's twice-a-day dosing was more convenient for patients.[25] Purdue's sales representatives promoted OxyContin to physicians as an initial opioid treatment for moderate-to-severe pain lasting more than a few days, to be prescribed instead of other single-entity opioid analgesics or short-acting combination opioid pain relievers. Purdue has stated that by 2003 primary care physicians had grown to constitute nearly half of all OxyContin prescribers, based on data from IMS Health, an information service providing pharmaceutical market research. DEA's analysis of physicians prescribing OxyContin found that the scope of medical specialties was wider for OxyContin than five other controlled-release, schedule II narcotic analgesics. DEA expressed concern that this resulted in

[25]Following OxyContin's July 2001 label change, Purdue modified its promotional messages but continued to focus on encouraging physicians to prescribe OxyContin for patients taking pain relievers every 4 to 6 hours. In 2003, Purdue began using the promotional claim "there can be life with relief" in OxyContin promotion.

information about the drug. For example, one section of the Web site did not disclose that OxyContin is not indicated for pain in the immediate postoperative period—the first 12 to 24 hours following surgery—for patients not previously taking the drug, because its safety in this setting has not been established. The Web site also did not disclose that OxyContin is indicated for postoperative pain in patients already taking the drug or for use after the first 24 hours following surgery only if the pain is moderate to severe and expected to persist for an extended period of time. Purdue voluntarily removed all sections of the Web site that were of concern to FDA.

FDA has also sent enforcement letters to other manufacturers of controlled substances for marketing and promotion violations of the FD&C Act. For example, in 1996, FDA issued an untitled letter to Zeneca Pharmaceuticals, at the time the promoter of Kadian,[41] for providing information about the drug to a health professional prior to its approval in the United States. Roxane Laboratories, the manufacturer of Oramorph SR, was issued four untitled letters between 1993 and 1995 for making misleading and possibly false statements. Roxane used children in an advertisement even though Oramorph SR had not been evaluated in children, and a Roxane sales representative issued a promotional letter to a pharmacist that claimed, among other things, that Oramorph SR was superior to MS Contin in providing pain relief. FDA has sent no enforcement letters to Ligand Pharmaceuticals concerning Avinza.

Purdue Distributed an OxyContin Video without FDA's Review That Appears to Have Made Unsubstantiated Claims and Minimized Risks

Beginning in 1998, Purdue, as part of its marketing and promotion of OxyContin, distributed 15,000 copies of an OxyContin video to physicians without submitting it to FDA for review. This video, entitled *I Got My Life Back: Patients in Pain Tell Their Story*, presented the pain relief experiences of various patients and the pain medications, including OxyContin, they had been prescribed. FDA regulations require pharmaceutical manufacturers to submit all promotional materials for approved prescription drug products to the agency at the time of their initial use. Because Purdue did not comply with this regulation, FDA did not have an opportunity to review the video to ensure that the information it contained was truthful, balanced, and accurately communicated. Purdue has acknowledged the oversight of not submitting the video to FDA for

[41]Zeneca Pharmaceuticals promoted Kadian for Faulding Laboratories, the drug's manufacturer at that time.

review. In February 2001, Purdue submitted a second version of the video to FDA, which included information about the 160-milligram OxyContin tablet. FDA did not review this second version until October 2002, after we inquired about its content. FDA told us it found that the second version of the video appeared to make unsubstantiated claims regarding OxyContin's effect on patients' quality of life and ability to perform daily activities and minimized the risks associated with the drug.

The 1998 video used a physician spokesperson to describe patients with different pain syndromes and the limitations that each patient faced in his or her daily activities. Each patient's pain treatment was discussed, along with the dose amounts and brand names of the prescription drugs, including OxyContin, that either had been prescribed in the past or were being prescribed at that time. The physician in the videos also stated that opioid analgesics have been shown to cause addiction in less than 1 percent of patients—a fact that FDA has stated has not been substantiated. At the end of the video, the OxyContin label was scrolled for the viewer.

In 2000, Purdue submitted another promotional video to FDA entitled *I Got My Life Back: A Two Year Follow up of Patients in Pain*, and it submitted a second version of this video in 2001, which also included information on the 160-milligram OxyContin tablet. Purdue distributed 12,000 copies of these videos to physicians. Both versions scrolled the OxyContin label at the end of the videos. FDA stated that it did not review either of these videos for enforcement purposes because of limited resources. Distribution of all four Purdue videos was discontinued by July 2001, in response to OxyContin's labeling changes, which required the company to modify all of its promotional materials, but copies of the videos that had already been distributed were not retrieved and destroyed.

FDA said that it receives numerous marketing and promotional materials for promoted prescription drugs and that while every effort is made to review the materials, it cannot guarantee that all materials are reviewed because of limited resources and competing priorities. FDA officials also stated that pharmaceutical companies do not always submit promotional materials as required by regulations and that in such instances FDA would not have a record of the promotional pieces.